DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 19, 2015

Creagh Medical, Ltd.
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K143561
Trade/Device Name: ELM PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 17, 2015
Received: April 20, 2015

Dear Ms. O'Connell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143561

Device Name
ELM PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The ELM Extension PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

510(k) Owner:	Creagh Medical IDA Business Park, Ballinasloe, Co. Galway, Ireland
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Summary Preparation Date:	December 23, 2014

2. Device Information

Device Trade Names:	ELM PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Dilatation Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code: DQY)

3. Predicate Devices

ELM PTA Balloon Dilatation Catheter predicate

Device Name:	ELM PTA Balloon Dilatation Catheter
510(k) Clearance Number:	K102645

4. Device Description

The Creagh Medical ELM Balloon Dilatation Catheter is a coaxial catheter with a semi compliant balloon near the distal tip. It is an Over-the-Wire (OTW) PTA device with shaft lengths of 40cm & 75cm. The ELM PTA Balloon Dilatation Catheter is compatible with a 0.035" guide wire.

The balloon has two radiopaque markers at either end of the balloon body that aid in the placement of the balloon within the stenosis. These two radiopaque marker bands indicate the dilating section of the balloon and aid in the balloon placement. The marker bands also indicate the nominal length of the balloon. The catheter tip is designed to ease entry into the peripheral arteries and to facilitate the crossing of tight stenosis. The clearance between the inner and outer catheter shaft acts as the passage for the inflation medium for balloon expansion. The proximal end of the catheter has a bifurcated manifold and strain relief that allows for the use of the 0.035" guidewire and the attachment of a balloon inflation device via

a standard luer connector. The inflation device is used to inflate and deflate the balloon with a contrast medium. The ELM PTA Balloon Dilatation Catheter is to be provided sterile (via ethylene oxide) and is intended for single use only.

The catheter is designed so that a specific balloon diameter can be reached depending on the Balloon size and defined pressure. A compliance chart is provided on the product label which provides the diameter of balloons at given pressures. Each product is packaged with a balloon protector which is positioned over the balloon for its protection prior to use. A re-wrap tool is also provided on the catheter shaft.

The accessories required by the physician but not included in the packaging are detailed below.

⇒ Introducer sheath in appropriate size and configuration for the selected vasculature
⇒ Syringes (10 – 20 cc)
⇒ Inflation device with manometer
⇒ Contrast medium
⇒ 0.035" Guidewire

The modified ELM 0.035" PTA Balloon Dilatation Catheter, hereafter referred to as ELM Extension, introduces 3 additional product codes with reduced Rated Burst Pressure as detailed below in Table 1.

Table: 1: ELM Extension Matrix

Balloon D x L (mm) x (mm)	Shaft Length	Min Rated Burst Pressure	Nominal Pressure	Sheath Size	Guide wire Size
12.0 x 40	75cm	18 ATM	12 ATM	7F	0.035"
14.0 x 40	75cm	16 ATM	10 ATM	8F	0.035"
16.0 x 40	75cm	14 ATM	10 ATM	8F	0.035"

The ELM 0.0035" PTA Balloon Dilatation Catheter matrix which was cleared in K102645 is detailed below in Table 2.

Table 2: ELM 0.0035" Catheter Matrix

BalloonD x L (mm) x (mm)	Shaft Length		Rated Burst Pressure	Nominal Pressure	Sheath Size	Guide wire Size
3.0 x 40	40cm	75cm	27 ATM	14 ATM	6F	0.035"
4.0 x 20	40cm	75cm	27 ATM	14 ATM	6F	0.035"
4.0 x 40	40cm	75cm	27 ATM	14 ATM	6F	0.035"
5.0 x 20	40cm	75cm	27 ATM	14 ATM	6F	0.035"
5.0 x 40	40cm	75cm	27 ATM	14 ATM	6F	0.035"
5.0 x 60	40cm	75cm	27 ATM	14 ATM	6F	0.035"
6.0 x 20	40cm	75cm	25 ATM	14 ATM	6F	0.035"
6.0 x 40	40cm	75cm	25 ATM	14 ATM	6F	0.035"
6.0 x 60	40cm	75cm	25 ATM	14 ATM	6F	0.035"
6.0 x 100	40cm	75cm	25 ATM	14 ATM	6F	0.035"
7.0 x 20	40cm	75cm	25 ATM	14 ATM	6F	0.035"
7.0 x 40	40cm	75cm	25 ATM	14 ATM	6F	0.035"
7.0 x 60	40cm	75cm	25 ATM	14 ATM	6F	0.035"
7.0 x 100	40cm	75cm	25 ATM	14 ATM	6F	0.035"
8.0 x 20	40cm	75cm	24 ATM	14 ATM	6F	0.035"
8.0 x 40	40cm	75cm	24 ATM	14 ATM	6F	0.035"
8.0 x 60	40cm	75cm	23 ATM	14 ATM	6F	0.035"

8.0 x 80	40cm	75cm	23 ATM	14 ATM	6F	0.035"
9.0 x 40	40cm	75cm	20 ATM	12 ATM	7F	0.035"
10.0 x 40	40cm	75cm	20 ATM	12 ATM	7F	0.035"
12.0 x 40	40cm	75cm	18 ATM	12 ATM	8F	0.035"

The 12.0x40 catheter size has a lower sheath compatibility than the previously approved ELM 12.0 * 40. The 14.0 X 40 and 16.0 x 40 are 2 new sizes with an increased balloon diameter.

5. Indications for Use

The ELM Extension PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

6. Substantial Equivalence

This Traditional 510(k) submission aims to demonstrate substantial equivalence of the ELM Extension PTA Balloon Dilatation Catheter with extended range through comparison with the predicate device – ELM PTA Balloon Dilatation Catheter cleared in K102645. Substantial equivalence is demonstrated for the intended use of the ELM device. Where substantial equivalence is not directly demonstrated from the perspective of technology and performance, design verification testing provides evidence of the safety and effectiveness of the ELM Extension device.

Technological differences between the subject and predicate devices have been evaluated through mechanical tests to provide evidence the ELM Extension Catheter is safe and effective as the ELM PTA Balloon Dilatation Catheter. The ELM Extension is substantially equivalent to the specified predicate device based on comparisons of device functionality, technological characteristics and indications for use. The ELM Extension device design has been verified and validated through the following mechanical tests:

- Working Length
- Radiopacity
- Tortuosity
- Catheter profile
- Guidewire passage
- Fatigue Testing
- Burst / Compliance Testing
- Tensile
- Inflation / Deflation
- Shelf Life Testing
- Simulate Use Testing
- Sheath Compatibility Testing

This verification and validation testing shows substantial equivalence through compliance of the ELM Extension to standards and specifications which the ELM predicate device was previously verified against. The results were shown to meet the specified acceptance criteria and did not raise new questions of safety or effectiveness, therefore, Elm Extension catheter is substantially equivalent to the ELM PTA Balloon Dilatation Catheter.